UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,234	04/06/2000	TSUTOMU AWAMURA	49668(281)	1287

21874 7590 11/14/2003

EDWARDS & ANGELL, LLP
P.O. BOX 9169
BOSTON, MA 02209

EXAMINER	
WHITE, EVERETT NMN	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/14/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/529,234	AWAMURA ET AL.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE f this c mmunication appears on the cover sheet with th correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6 and 8-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The amendment filed September 2, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Claims 4 and 7 have been canceled; Claim 12 was previously canceled;
(B) Claims 1-3, 5, 6 and 8-11 have been amended;
(C) Comments regarding the Office Action have been provided drawn to:
  (i) 112, 2nd paragraph rejection, which has been maintained in part;
  (ii) 103(a) rejection, rendered moot by new ground of rejection over newly cited US Patents.

2. Claims 1-3, 5, 6 and 8-11 are pending in the case.

3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 1-3, 5, 6 and 8-11 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 1 and 2, the term "solid solution" is not clear since one is not able to ascertain whether the claim is referring to a solid or solution. This term renders claims 1 and 2 indefinite. Claims 3-11 are also rejected since Claims 3, 5, 6 and 8-11 are dependent from Claims 1 and 2 and this term is not clarified in these claims.

In Claim 11, the passage "the additional edible polymer is hydroxypropyl cellulose" lacks clear antecedent basis by being dependent from Claim 1 since "additional edible polymer" is not mentioned in Claim 1. In Claim 11, the passage "the starch syrup is reducing maltose starch syrup" also lacks clear antecedent basis by being dependent from Claim 1 since "starch syrup" is not mentioned in Claim 1. It appears that Claim 11 should be dependent from Claim 10.

R sponse to Arguments Under 35 U.S.C. 112, 2nd Paragraph

5. Applicant's arguments filed September 2, 2003 have been fully considered but they are not persuasive. Applicants argument regarding the term "solid solution" in their

response filed September 9, 2003 have been carefully considered. It is noted that the term "solid solution" has not been clearly defined in the instant specification. A copy of the reference mentioned in Applicants arguments "WordNet 1.7, copyright 2001; Princeton University", which is suggested as setting forth the definition of the term "solid solution" is requested for review.

Claim Rejections - 35 USC § 103

6. Claims 1-3, 5, 6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al (US Patent No. 6,042,844, newly cited) in view of Squillante et al (US Patent No. 6,106,856, newly cited).

Applicants claim a water soluble film preparation for oral administration comprising a drug, an edible polymer and a monsaccharide or an oligosaccharide, wherein the film is obtained by spreading and drying and has an elution rate of more than about 50% per 10 minutes and the drug is a compound enhanced in internal absorption by forming a solid solution with the edible polymer in which the compound is at least one of nilvadipine, nifedipine, phenytoin or griseofulvin. Additional limitations include weight percent of the content of the drug, edible polymer, and monosaccharide or oligosaccharide in the soluble film preparation and recitation of specific edible polymers and oligosaccharides.

The Ishida et al patent discloses sheet pacts that are used to supply moisture to skin and further discloses beginning at column 1, line 64, process steps for preparing sheet packs, which include spreading and drying a thin film of a film-forming paste-like cosmetic substance, which includes a water-soluble polymer and water as main components; for example, a dry film-like cosmetic article mainly composed of a water-soluble polymer including medical or cosmetic components. See column 7, lines 43-50, wherein the film forming cosmetic substance includes a film-forming agent that may be selected as polyvinyl pyrrolidone and a thickening agent that may be selected as methylcellulose, hydroxyethylcellulose or hydroxypropylcellulose. See column 7, lines 64-66 wherein the film-forming cosmetic substance may comprise a humectant that may be selected as monosaccharides and polysaccharides such as maltose. The

ingredients used to prepare the film-forming cosmetic substance of the Ishida et al patent are set forth in the film preparation of the instant claims. The instantly claimed water soluble film preparation differ from the Ishida et al patent by claiming the presence of at least one drug or compound selected from nilvadipone, nifedipine, phenytoin or griseofulvin. However, the Squillante et al patent shows that the presence of a drug that may be selected as nifedipine in a film for trandermal delivery is known in the art. See example 2 of the Squillante et al patent wherein an adhesive film preparation is carried out, which comprises nifedipine, wherein the film is tested on hairless mouse skins to evaluate their suitability as delivery devices.

One of ordinary skill in this art would be motivated to combine the teachings of the Ishida et al patent with the teachings of the Squillante et al patent since both patents set forth films as delivery devices through skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate into the film preparation set forth in the Ishida et al patent nifedipine as an ingredient in the film in view of the recognition in the art, as evidenced by the Squillante et al patent, that nifedipine is a compound that is effective for the treatment of hypertension or angina pectoris by topical applications.

7. Applicant's arguments with respect to Claims 1-3, 5, 6 and 8-11 have been considered but are moot in view of the new ground(s) of rejection.

8. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al (US Patent No. 6,042,844, newly cited) in view of Squillante et al (US Patent No. 6,106.856, newly cited) as applied to Claims 1-3, 5, 6 and 8-11 above, and further in view of Fuchs et al (US Patent No. 4,136,145, already of record).

Applicants claim a water soluble film preparation for oral administration comprising a drug, an edible polymer and a monsaccharide or an oligosaccharide, wherein the film is obtained by spreading and drying and has an elution rate of more than about 50% per 10 minutes and the drug is a compound enhanced in internal absorption by forming a solid solution with the edible polymer in which the compound is at least one of nilvadipine, nifedipine, phenytoin or griseofulvin. Additional limitations in

the dependent claims include weight percent of the content of the drug, edible polymer, and monosaccharide or oligosaccharide in the soluble film preparation and recitation of specific edible polymers and oligosaccharides.

The information set forth in the above rejection of the claims over the Ishida et al and Squillante et al patents is incorporated into the current rejection. The instant claims differ from the Ishida et al and Squillante et al patents by specifying the film as having a specific content of the drug, edible polymer and monosaccharide or oligosaccharide.

The Fuchs et al patent discloses admixtures of medicament and carriers in the form of a film wherein the active substance is incorporated therein (see abstract). See column 2, 5th and 6th paragraph for a list of active medicament compounds that may be incorporated into the film. The medicament compounds disclosed in the Fuchs et al patent embrace the drug set forth in the instantly claimed invention. The Fuchs et al patent also indicates the presence of film forming polymers that are known in the art, which include poly-N-vinyl-pyrrolidone, methyl-cellulose, ethyl-cellulose, hydroxyalkyl ethers of cellulose such as hydroxypropyl-cellulose and hydroxy-ethyl-cellulose (see the first paragraph of column 3). Fuchs et al further discloses fillers that may be included with the film that may be selected from lactose, dextrose, starches and mannitol (see column 3, 4th paragraph). The above listed film forming polymer and fillers of the Fuchs et al patent embrace the edible polymer, monosaccharide, oligosaccharide or maltose starch syrup of the instantly claimed invention. The Fuchs et al patent discloses that the proportion of pharmaceutically active ingredients in the film may be from a pharmaceutically effective trace amount up to about 60% by weight of the film, which covers the amount of drug set forth in instant Claim 2. The Fuchs et al patent also discloses 6-20% by weight of the film-forming polymer and up to 30% by weight of a filler, which is within the range of the amount of edible polymer and monosaccharide or oligosaccharide that is set forth in instant Claim 2. The Fuchs et al patent discloses medicinally active substances that may be admixed in a film (see column 2, lines 60-64).

One of ordinary skill in this art would be motivated to combine the teachings of the Ishida et al, Squillante et al and Fuchs et al patents in a rejection of the instant

claim nder 35 U.S.C. 103 since each patent discloses compositions in the form of water-soluble films comprising a pharmaceutical component incorporated into the film.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time e invention was made to incorporate into the film preparation set forth in the proce s of the Ishida et al patent in view of the Squillante et al patent, specific contents of dr edible polymer and monosaccharide or oligosaccharide in view of the recoo ition in the art, as suggested in the Fuchs et al patent, that the indicated contents are safe and effective for the preparation of pharmaceutical composition in the form of films

9. Applicant's arguments with respect to Claims 1-3, 5, 6 and 8-11 have been cons lered but are moot in view of the new ground(s) of rejection.

Summary

10. All the claims are rejected.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this O ffice action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 7 7(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 136(a).

A shortened statutory period for reply to this final action is set to expire THREE MON S from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the short d statutory period will expire on the date the advisory action is mailed, and any extens on fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the a isory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's Telephone Number, Fax Number, and Oth r Information

12. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White
E.White

James O. Wilson
Supervisory Primary Examiner
Technology Center 1600